

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: NATIONAL PRESCRIPTION)	MDL No. 2804
OPIATE LITIGATION)	
)	Case No. 17-md-2804
)	
This document applies to All Cases.)	Judge Dan Aaron Polster
)	

AMENDED NOTICE OF ARCOS DISCLOSURE

COMES NOW, the Plaintiffs, by and through Co-Leads and the Plaintiffs' Executive Committee, and pursuant to the *Protective Order Re: DEA's ARCOS/DADS Database* (Doc. #167), the *Order Regarding Plaintiffs' Motion for Modification of CMO-1* (Doc. #739), and consultation with parties of interest, gives notice of this amended procedure to share with all MDL Plaintiffs' counsel reports derived from the ARCOS data that lists, for each county, all manufacturers, distributors, and pharmacies that contributed directly to the presence of opioids in that county.

For MDL Plaintiffs' counsel to request and obtain said reports, Requesting Counsel must a) review and execute the ARCOS Protective Order attached hereto as Exhibit A; b) complete and execute the affidavit attached hereto as Exhibit B affirming that Requesting Counsel represents one or more MDL Plaintiffs and list such Plaintiffs; c) complete the ARCOS Information Request Form attached hereto as Exhibit C; and d) submit via email to arcosrequest@levinlaw.com the executed Exhibits A, B, and C. Once a valid request is received, the reports for the requested counties will be provided to Requesting Counsel via email in PDF

format which shall be properly designated as CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER.

The reports which will be made available are more fully described below:

Distributor List:

This list includes the name and address for all ARCOS registrants and reportersⁱ that distributedⁱⁱ any of the 8 Opioid drug families within the country according to the 2006-2014 DEA's ARCOS data. The 8 drug families include Buprenorphine, Fentanyl, Hydrocodone, Hydromorphone, Morphine, Oxycodone, Oxymorphone, and Tapentadol.

Pharmacy List:

The list includes the name and address for all DEA registrants identified as a Chain Pharmacy or Retail Pharmacy located within the county that purchased any of the 8 Opioid drug families from a distributorⁱⁱⁱ according to the 2006-2014 DEA's ARCOS data. The 8 drug families include Buprenorphine, Fentanyl, Hydrocodone, Hydromorphone, Morphine, Oxycodone, Oxymorphone, and Tapentadol.

Manufacturer List:

This list includes the names of all identified labelers^{iv}, based on the Food and Drug Administration's National Drug Code (NDC), of any of the 8 Opioid drug families that were

ⁱ DEA issues a *separate* registration to manufacturers and distributors of controlled substances for *each* location in which controlled substance activity occurs. Therefore, manufacturers and distributors may hold multiple registrations *simultaneously*. Each individual registration is identified by a unique registration number. An ARCOS registrant is a manufacturer or distributor required to report controlled substance inventories and transactions to DEA (ARCOS). An ARCOS reporter is an entity that files controlled substance transaction and inventory reports with DEA (ARCOS). An ARCOS registrant reporting *only its own* controlled substance transactions and inventories to DEA (ARCOS) is a single reporter. A registered central reporter *has* a DEA registration as a manufacturer or distributor and reports controlled substance transactions and inventories for *itself and other* ARCOS registrants within its corporate structure. ARCOS Registrant Handbook at 1-5; 2-2 – 2-3 available at <https://www.deadiversion.usdoj.gov/arcos/handbook/full.pdf#search=arcos%20handbook>. The ARCOS Reporters with a listed business activity of "Distributor" was used to create this list.

ⁱⁱ The distributor list includes any ARCOS Reporter with a "Reporter Business Activity" of "Distributor" who reported a Transaction code S (Sale, Disposition, or Transfer). *Transaction code S* is used when a controlled substance is physically transferred to another DEA registrant. ARCOS Registrant Handbook at 5-14. This list includes only Transaction code S sale transactions to buyers with any of the following buyer business activity designations: PRACTITIONER; RETAIL PHARMACY; PRACTITIONER-DW/100; CHAIN PHARMACY; HOSPITAL/CLINIC; HOSP/CLINIC-VA; CENTRAL FILL PHARMACY; HOSP/CLINIC- MIL; HOSP/CLINIC FED; MLP-AMBULANCE SERVICE; PRACTITIONER-DW/275; MLP-NURSE PRACTITIONER; MLP PHYSICIAN ASSISTANT; AUTOMATED DISPENSING SYSTEM; MLP-PHYSICIAN ASSISTANT-DW/30; PHARMACY- MIL; PRACTITIONER-MILITARY; MLP-OPTOMETRIST; MLP-NATUROPATHIC PHYSICIAN; MLP-PHYSICIAN ASSISTANT-DW/100; PHARMACY – FED; CHAIN HOSP/CLINIC; MLP REGISTERED PHARMACIST; MLP-NURSING HOME; MLP-NURSE PRACTITIONER-DW/100; MLP-DEPT OF STATE; MLP-MILITARY;

ⁱⁱⁱ Distributor here includes any ARCOS reporter with a "Reporter Business Activity" of "Distributor".

^{iv} The labeler information was derived using the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration code for each drug and cross referencing against the Food and Drug Administration, National Drug Code Directory and list of NDC/NHRIC Labeler Codes. List of

distributed^v within the county according to the 2006-2014 DEA's ARCOS data. The 8 drug families include Buprenorphine, Fentanyl, Hydrocodone, Hydromorphone, Morphine, Oxycodone, Oxymorphone, and Tapentadol.

Respectfully submitted,

/s/ Peter J. Mougey

Peter J. Mougey, Esq.

LEVIN, PAPANTONIO, THOMAS, MITCHELL,
RAFFERTY & PROCTOR, P.A.

316 South Baylen Street, Suite 600

Pensacola, Florida 32502

Telephone: (850) 435-7068

Facsimile: (850) 436-6086

pmougey@levinlaw.com

*Plaintiff's Executive Committee
Member*

NDC/NHRIC Labeler Codes available at

<https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm191017.htm>.

Food and Drug Administration, *National Drug Code Directory* available at:

<https://www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt>

<https://www.deadiversion.usdoj.gov/arcos/ndc/readme.txt>

Additionally, the ARCOS Registrant Handbook provides the following definitions relating to labeler: A packer/repacker is a registrant that packs a product into a container (i.e., packer) or repacks a product into different size containers, such as changing a package of 50 capsules to 5 packages of 10 capsules each. A labeler/relabeler is a registrant that affixes the original label to a product (i.e., labeler) or changes in any way the labeling on a product without affecting the product or its container (i.e., relabeler). The "relabel" term implies that the package size remains unchanged with changes being made only in brand name, NDC number, distributor, etc. ARCOS Registrant Handbook at 6-2, available at

<https://www.deadiversion.usdoj.gov/arcos/handbook/full.pdf#search=arcos%20handbook>.

^v The Manufacturer list includes any labeler identified on any NDC code which was distributed within the county and reported with a Transaction code S (Sale, Disposition, or Transfer). Transaction code S is used when a controlled substance is physically transferred to another DEA registrant. ARCOS Registrant Handbook at 5-14. This list includes only Transaction code S sale transactions to buyers with any of the following buyer business activity designations: PRACTITIONER; RETAIL PHARMACY; PRACTITIONER-DW/100; CHAIN PHARMACY; HOSPITAL/CLINIC; HOSP/CLINIC-VA; CENTRAL FILL PHARMACY; HOSP/CLINIC- MIL; HOSP/CLINIC FED; MLP-AMBULANCE SERVICE; PRACTITIONER-DW/275; MLP-NURSE PRACTITIONER; MLP-PHYSICIAN ASSISTANT; AUTOMATED DISPENSING SYSTEM; MLP-PHYSICIAN ASSISTANT-DW/30; PHARMACY- MIL; PRACTITIONER-MILITARY; MLP-OPTOMETRIST; MLPNATUROPATHIC PHYSICIAN; MLP-PHYSICIAN ASSISTANT-DW/100; PHARMACY – FED; CHAIN HOSP/CLINIC; MLP-REGISTERED PHARMACIST; MLP-NURSING HOME; MLP-NURSE PRACTITIONERDW/100; MLP-DEPT OF STATE; MLP-MILITARY;

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 7th day of August, 2018, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF System. Copies will be served upon counsel of record by, and may be obtained through, the Court CM/ECF Systems.

/s/ Peter J. Mougey

Peter J. Mougey, Esq.

*Plaintiff's Executive Committee
Member*